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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,574	11/28/2003	Allan Tanghoj	P66852US3	4958
136	7590	09/08/2008	EXAMINER	
JACOBSON HOLMAN PLLC			GILBERT, ANDREW M	
400 SEVENTH STREET N.W.				
SUITE 600			ART UNIT	PAPER NUMBER
WASHINGTON, DC 20004			3767	
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			09/08/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/722,574	TANGHOJ ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	ANDREW M. GILBERT	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 11 July 2008.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 2-5 and 7-11 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,6 and 12-20 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 6/23/2005 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____ .  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/25/08, 7/11/08</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____ .                                  |

## **DETAILED ACTION**

### ***Acknowledgements***

1. This office action is in response to the reply filed on 6/25/2008.
2. In the reply, the applicant amended claims 1, 13-15, 17-19.
3. Claims 2-5, 7-11 remain withdrawn.
4. Thus, claims 1, 6, 12-20 are pending, with claims 1 and 19 being independent.

### ***Information Disclosure Statement***

5. The information disclosure statement (IDS) submitted on 6/25/08, 7/11/08 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Specification***

6. The amendment filed 6/25/2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The tubular member having a closed end distal from the open end so that when the tubular protective member is connected to the 2<sup>nd</sup> catheter section, both ends of the annular cavity are closed preventing a friction-reducing substance from escaping through either one of the ends as shown in Figs 4-7. The amendment is not supported by the original disclosure in conjunction with Figs 12 and 13. The Examiner notes that the drawings further do not clearly set forth the proposed amendment in Figs 12-13 (e.g. the Examiner can clearly tell the end has a flange, however, cannot clearly tell that the end is closed) and the

original disclosure does not support the current amendment or reference that the embodiment of Figs 12-13 are similar in any regard to Figs 4-7.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 14, 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment that the tubular protective member has a closed end distal from said joint, such that, when the tubular protective member is connected to the joint, both ends of the annular cavity are closed so as to prevent any friction-reducing substance accommodated in the annular cavity from escaping through either one of said ends. The closed distal end and sealed annular cavity are not supported in the originally filed specification in relation to the elected embodiment Figs 12-13.

9. Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.  
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1, 12, 13, 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Juster et al (3934721). In reference to claims 1 and 19, Juster et al discloses a kit for preparing a catheter for draining a human bladder, the kit comprising at least a first proximal catheter section (31) and a second distal catheter section (35); said two catheter sections defining a longitudinally extending passage therein configured to receive a flow of urine therethrough from a proximal end portion of said first catheter section which is inserted into a human urethra to a distal end of said second catheter section, the sections being fixedly connected by a joint (see transition between 31 and 35; wherein the Examiner notes that Webster's defines "joint" as "a place where two things or parts are joined"; in the instant case, parts 31, 35 are two distinct parts joined by the beveled transition. The Examiner recommends further structurally defining the joint to overcome the prior art of record) and arranged in a coextending fashion with a tubular protective member (Fig 3) surrounding said first catheter section, said second distal catheter section being not covered so as to be exposed to the environment when said kit is configured for storage (Fig 1), the kit further including a joint defining a substantially liquid tight seal (the beveled joint joining 13 and 15 forms a substantially liquid tight frictional fit seal with the proximal end (25) of the tubular protective member (21)) at a distal end of a substantially annular and longitudinally extending cavity

provided between the proximal end portion of the first catheter section and an inner wall of the tubular protective member (the beveled joint joining 13 and 15 forms a substantially liquid tight frictional fit seal with the proximal end (25) of the tubular protective member (21); Fig 1), the tubular protective member having an open end (Fig 4) that is removably connected to the second catheter section (Fig 3-4) and a closed end distal from said open end (25), so that, when the tubular protective member is connected to the joint (Fig 3) both ends of the annular cavity are closed so as to prevent any friction-reducing substance accommodated in the annular cavity from escaping through either one of said ends (Fig 3; col 2, Ins 56-63) removed, said proximal end portion of the first catheter section being exposed to the environment and ready for insertion into the human urethra (Fig 1-2, col 1-2) only when the tubular protective member is completely removed.

12. In reference to claim 12 and 20, Juster et al additionally discloses wherein the catheter has a hydrophilic surface and a liquid swelling medium is provided in the annular cavity (col 2, Ins 56-63).

13. In reference to claim 13, Juster et al additionally discloses wherein the tubular protective member is detachably attached to an outer surface of the catheter when the tubular protective member is covering the first catheter section (Fig 3).

14. In reference to claim 18, Juster et al additionally discloses wherein the open end of the tubular protective member fastens to said second catheter section when the tubular protective member is covering the first catheter section (Fig 3).

15. Claims 1, 6, 12-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Pedersen et all (3934721). In reference to claims 1 and 19, Pedersen et al discloses a kit for preparing a catheter for draining a human bladder, the kit comprising at least a first proximal catheter section (1) and a second distal catheter section (3); said two catheter sections defining a longitudinally extending passage therein configured to receive a flow of urine therethrough from a proximal end portion of said first catheter section which is inserted into a human urethra to a distal end of said second catheter section, the sections being fixedly connected by a joint (Fig 1; see transition between 1 and 3; wherein the Examiner notes that Webster's defines "joint" as "a place where two things or parts are joined"; in the instant case, parts 1, 3 are two distinct parts joined by the beveled transition. The Examiner recommends further structurally defining the joint to overcome the prior art of record) and arranged in a coextending fashion with a tubular protective member (4) surrounding said first catheter section, said second distal catheter section being not covered so as to be exposed to the environment when said kit is configured for storage (3; Fig 1), the kit further including a joint defining a substantially liquid tight seal (the beveled joint joining 1 and 3) forms a substantially liquid tight frictional fit seal with the proximal end (interaction between 9 and 10; Fig 1, 9-10) of the tubular protective member (4) at a distal end of a substantially annular and longitudinally extending cavity provided between the proximal end portion of the first catheter section and an inner wall of the tubular protective member (between 9 and 10; Fig 1, 9-10), the tubular protective member having an open end (9, 4, e.g. Fig 4) that is removably connected to the second catheter section (Fig 1, 9-10) and a closed end

distal from said open end (7; Fig 1), so that, when the tubular protective member is connected to the joint (Fig 1) both ends of the annular cavity are closed so as to prevent any friction-reducing substance accommodated in the annular cavity from escaping through either one of said ends (col 3, lns 26-39; col 5, lns 15-29) removed, said proximal end portion of the first catheter section being exposed to the environment and ready for insertion into the human urethra (Fig 1, 5, 8; Summary) only when the tubular protective member is completely removed.

16. In reference to claim 6, 15, Pedersen et al additionally discloses the distal end of the 2nd catheter section is provided with a removable liquid tight seal or foil (11).

17. In reference to claim 12 and 20, Pedersen et al additionally discloses wherein the catheter has a hydrophilic surface and a liquid swelling medium is provided in the annular cavity (col 3, lns 26-39; col 5, lns 15-29).

18. In reference to claim 13, Pedersen additionally discloses wherein the tubular protective member is detachably attached to an outer surface of the catheter when the tubular protective member is covering the first catheter section (Fig 1, 5, 8, 9).

19. In reference to claim 14, Pedersen et al additionally discloses an outward flange on the tubular protective member at the closed end (7; Fig 1)

20. In reference to claim 16, Pedersen et al additionally discloses a ribbed portion between said 1st and 2nd sections (Fig 1, 9, 10).

21. In reference to claim 17, Pedersen et al additionally discloses the open end of the tubular protective member fasted to said 2<sup>nd</sup> catheter section via engagement with said ribbed portion (Fig 1, 9-10).

22. In reference to claim 18, Pedersen et al additionally discloses wherein the open end of the tubular protective member fastens to said second catheter section when the tubular protective member is covering the first catheter section (Fig 1, 5, 8, 9).

### ***Double Patenting***

23. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

24. Claims 1, 6, 12-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26, 54-65 of copending Application No. 10/184081 or claims 1-21 of copending Application No. 10/537014. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the present application are merely broader than the copending parent case. Thus, the invention claimed in the current

application is merely generic to the species claimed in the parent application and it has been held that the generic invention is anticipated by the species.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Response to Arguments***

25. Applicant's arguments with respect to claims 1, 6, 12-20 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO 892 form.

27. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/  
Examiner, Art Unit 3767  
/Kevin C. Sirmons/  
Supervisory Patent Examiner, Art Unit 3767